REMARKS/ARGUMENTS

Claims 15-32 are pending in this application. Claims 1-14 have been canceled. Claim 22 has been amended.

Claim 22 has been amended by substituting "varying" for the passive wording "is varied", and applicant submits that the formal objection to claim 22 is thereby overcome.

The present invention as defined by the pending claims recognizes that when a muscle is continuously stimulated with electrical stimulation in accordance with a fixed pattern, the muscle can become accustomed to the stimulation so that it no longer reacts in the appropriate manner. In order to prevent the muscle from becoming accustomed to the electrical stimulation, the present invention proposes that either all of the parameters listed, or a selection of these parameters, be intentionally varied in accordance with a predetermined pattern or randomly within pre-specified limits in the course of a long treatment in order to prevent the muscle affected by the electrical stimulation and the body's response to the muscle contraction from getting used to the fixed pattern of electrical stimulation. The stimulation pulses or groups of pulses are repeated in synchronization with the heart rate and, in particular, relative to the T-wave.

More specifically, independent apparatus claim 15 requires that each pulse or group of pulses is administered within "a range from 5 % of the R-R path length before the expected end of the T-wave up to 45 % of the R-R path length after the end of the T-wave", i.e. once per heart beat cycle relative to the T-wave. In humans the heart rate lies in the range from approximately 40 beats per minute (bpm) (which is equivalent to 2/3 beats per second or 2/3 Hz) up to around 200 bpm (or 3 Hz) when exercising. For different types of mammals the heart rate ranges from approximately 20 bpm (or 1/3 Hz) (e.g. whales) up to around 450 bpm (or 7.5 Hz) (e.g. hamsters), such that the frequency of the administered pulses or groups of pulses is in the range of 1/3 Hz to 7.5 Hz, if the stimulation is continuously administered using the electrotherapy apparatus of the present invention.

In accordance with the present invention, the stimulation pulses administered to the person or the mammal are varied in different ways to prevent the muscles from getting accustomed to the types of pulses administered. Thus, pursuant to independent apparatus claim 15, one or more of the following may be varied:

a. the amplitude of the stimulation pulses;

b. the pulse repetition frequency of the stimulation pulses (such as, for example, 1 pulse per heart beat, 1 pulse for every second heart beat, 1 pulse for every third heart beat, 1 pulse for a random number of heart beats, etc.), but all pulses are synchronized to the T-wave;

c. the repetition frequency of each group of pulses - if a group of pulses is used - once per heart beat or once every few heart beats, etc.;

d. the duration of each stimulation pulse or group of stimulation pulses;

e. the time offset relative to the end of the T-wave.

Thus the pulse may not only be varied in amplitude, or relative to the T-wave, but also a small group of pulses can be administered relative to the T-wave, however, this group of pulses is administered using a repetition frequency appropriate for the relevant mammal (i.e. in the range of 1/3 Hz to 8 Hz), even if the group of pulses may use a different pulse repetition frequency for the pulses of each group during the duration of that stimulation. However, the group repetition frequency of the group of pulses is still only administered in the earlier mentioned frequency range (1/3 Hz to 8 Hz).

In contrast to this, May (all references to "May" are to U.S. patent 7,418,294, which was published as US 2003/0176901, and which has been made of record herein with the attached IDS) discloses an electro-therapeutic device for the treatment of preferably the human body "with electrical currents having a defined frequency and amplitude" (see column 1, lines 14-16 of May). The only reference in May to a human heart concerns the selection of the frequency range of the stimulation used by May and discusses this frequency range relative to "cardiac ventricular fibrillation" (column 4, lines 44-45). The frequency range used in May is in the range of 4,096 Hz to 32,768 HZ (column 8, line 21) and, in claim 1, in the range of 1 kHz up

to 100 kHz, that is, 1,000 Hz to 100,000 Hz. Moreover, the electro-therapeutic device used in May is intended for the following treatments (column 4, lines 51-64 of the US patent):

"A device as defined by the invention is intended for primarily treating the following:

Painful diseases of the joints such as arthroses;

pain in the back and the neck with related diseases of the spine;

muscle distortions;

pain and swelling after injuries and surgical interventions, including fading of the effects of local anesthetics, among others;

normal, retarded and permanent healing processes, for example effusions of blood, bone fractures, ulcers of the lower leg, and pressure sores;

venereal diseases and edemas."

Thus, May is not directed to curing adverse conditions of the human or mammalian heart as is the case in the present application.

May, including claim 1 thereof, discloses the capability of being able to vary the parameters of stimulation of an electro-therapeutic device, however, this variation is not coupled to the variation in heart rate of the patient. To the contrary, in May the variation of the devices parameters is such that when the frequency of stimulation is varied, the corresponding stimulation current is simultaneously varied; i.e. as the frequency of stimulation is increased, the current for each stimulation pulse is reduced to prevent the patient from being harmed by too large a current.

Thus the electro-therapeutic device disclosed in May provides stimulation pulses which are determined by an operator of the device, who varies the frequency of stimulation and hence the current by e.g. manually turning a knob. This is contrary to claim 15 of the present application, which recites in relevant parts to "vary at least one of said amplitude, said pulse repetition frequency, said duration and said offset in accordance with a predetermined pattern stored in a microprocessor or a random number generator ...."

For at least this reason, claim 15 is not anticipated by May.

In addition, and independent of the foregoing, there is no mention of the human heart in May per se, and there is no discussion, mention or suggestion in May to provide the stimulation pulses with "a time offset relative to a predicted end of a T-wave of an electrocardiogram derived from said person or mammal" as recited in claim 15.

For at least this additional reason, claim 15 is not anticipated by May.

Still further, there is no discussion, mention or suggestion in May that this "offset [lies] in a range from 5 % of the R-R path length before the expected end of the T-wave up to 45 % of the R-R path length after the end of the T-wave" as also required by claim 15.

For at least this further reason, claim 15 is not anticipated by May.

As repeatedly held by the Federal Circuit Court of Appeals, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, for anticipation the "identical invention must be shown in as complete detail as is contained in the ... claim". *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236; 9 USPQ2d 1913, 1920 (Fed. Circ. 1989). MPEP §2131.

As above discussed and demonstrated, May does not meet the test for anticipation required by the Federal Circuit cases.

For any and all of the foregoing reasons, claim 15 is not anticipated by May.

The same applies to independent method claim 22, which, though employing method terminology, includes the same limitations as discussed above in relation to claim 15.

Thus, independent claims 15 and 22 are not anticipated by May.

Claims 17 and 24, which depend from claims 15 and 22, respectively recite that the pulse repetition frequency lies in the range from 20 to 1,000 Hz and that this frequency can be varied within this range. As discussed at some length above, the frequency range recited in May is far above the frequency range recited in claims 17 and 24. Accordingly, claims 17 and

24 are not anticipated by May, in addition to the fact that their respective parent claims 15 and 22 are not anticipated for the reasons stated above.

In the context of the anticipation rejection of claim 15, applicant points to the sole implied reference to the human heart in May (column 4, lines 41-45): *"The selection of this frequency range ensures that the reduced capability of introducing current at lower frequencies is avoided, and that the required "distance" from the threshold of cardiac ventricular fibrillation is maintained."*, to the effect that the frequency of pulsation should be chosen such that it is significantly distant from the threshold of cardiac ventricular fibrillation to prevent the heart from being damaged during the stimulation of a patient.

A person of ordinary skill in the art knows that the frequency of cardiac ventricular fibrillation is generally in the range of 4 Hz to 6 Hz for humans, i.e. just 2 Hz above the actual repetition frequency of the stimulation pulses used to treat humans using the apparatus of the present invention and, moreover, is exactly in the frequency range used to treat mammals such as e.g. dogs, and May specifically warns against using this range, i.e. by maintaining a significant "distance from the threshold of cardiac ventricular fibrillation".

Furthermore, May does not disclose or in any form suggest the possibility of synchronizing the stimulation pulses to the heart rate. May also does not disclose or suggest that when continuously repeating stimulation pulses are issued the pulses should be interrupted once per heart beat, or once per several heart beats, or randomly to obtain groups in synchronization with the T-wave, or that the pulse repetition frequency of the group of pulses can be varied as can its amplitude or its duration, etc.

Thus the person of ordinary skill in the art is taught by May that an electrotherapy apparatus should be designed such that the stimulation pulses do not influence the human heart rate; i.e. the stimulation pulses should be chosen such that they are repeated significantly faster than the human heart rate so as not to interact with this, but not, as is the case in the present invention, in synchronization to this.

CONCLUSION

In view of the foregoing, applicant submits that this application is in condition for allowance, and a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 273-4730 (direct dial).

Respectfully submitted,

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